Dynamic standing frame

ACTIVALL™

CE

USER MANUAL AND MAINTENANCE GUIDELINES

AKCESMED®

CAUTION! Manufacturer takes responsibility for proper usage of the device only when the product was purchased from qualified Akces-Med employee or at specialized medical store.

Medical product first class according to the Regulation 93/42/EWG of European Parliament and Council regarding medical products.
For this product the producer issued relevant declaration of conformity.
Producer's identification number in the Registration Department of Healing Products, Medical Products and Biocide Products:

PL/CA01 04088/W

QUALITY MANAGEMENT SYSTEM ISO 13485

ISO 13485
CERTIFIED COMPANY

Akces-Med Sp. z o.o. Company introduced quality management system ISO 13485 regarding production, sales and service.
The system is certified by Det Norske Veritas..

AKCESMED

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INTRODUCTION

The dynamic verticalizer ACTIVALL was designed to help in rehabilitation of people with paresis of lower limbs as well as trunk and to enable standing in upright position and walking. We did our best to give you the product which is functional, ergonomic and safe. The advantages of our verticalizer are: light and stable base, easy regulation of hip clamping-ring and chest clamping-ring, solid closings etc.

Please read this instruction manual carefully. You will find information about our product and will learn how to use it safely and efficiently.

If you have any questions or comments please contact our Medical Adviser at (tel. +48 0508 382 502) or directly AKCES - MED Ltd. at (tel. +48 017 85 00 978).

We thank you for purchasing our product.

CAUTION! Before using the product, user is obliged to familiarize himself/herself with user manual. Remember that complying with guidelines is highly important. It assures safety and extends durability as well as aesthetics of the device.

1. Purpose of the instruction

This instruction contains all basic information needed to use verticalizer ACTIVALL properly, preparation before using the device, rules of patient's preparation, ways of maintenance and cleaning and the conditions of guarantee. It should be kept in a readily available place. The instruction is dedicated to disabled persons who use dynamic verticalizer ACTIVALL and persons who directly take care of the disabled as well as to doctors and physiotherapists.

Before taking any action with the device, you must read the content of this instruction and make sure that all the information, recommendations and warnings contained in it are fully comprehensible.

2. Recommendation of the usage the verticalizer Activall

Clinical trials which were conducted on static and dynamic verticalizers confirmed the recommendations of use of these devices in treatment and preventive treatment of many various illnesses, particularly in :

- improvement of action of cardiovascular system,
- preventive treatment and treatment of venous stagnations,
- improvement of lungs ventilation and preventive treatment of pneumonia,
- preventive treatment of pulmonary artery embolias,
- preventive treatment and treatment of osteoporosis,
- preventive treatment and treatment of urinary system stagnations,
- improvement of peristalsis of intestines,
- help in re-education of neurogenic vesicle,
- improvement of psychic condition,
- preventive treatment of amyotrophy,
- preventive treatment and treatment of contractures, improvement of joints movability.

The decision to define the form of rehabilitation, including use of verticalizer must always be made by a leading doctor.

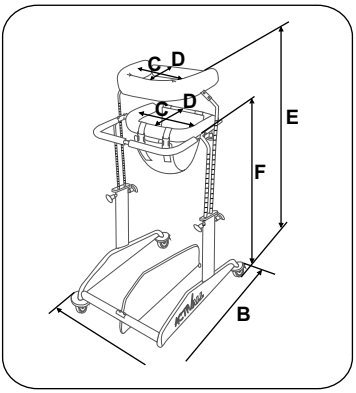
3. General characteristic of dynamic verticalizer ACTIVALL

Dynamic verticalizer ACTIVALL is intend for active rehabilitation of disabled people with paresis of bottom limbs and trunk.
The device permits disabled person to walk forward and backward, stand independently and safely (although under supervision) or with others' help and do simple activities of everyday life in straight erect position.
Thanks to its simplicity verticalizer ACTIVALL is unusually valuable device during rehabilitation of the disabled at home, in hospital or rehabilitation centers' conditions. The proper use of it may contribute to a considerable improvement of the quality of disabled persons' life.

4. Technical specification of verticalizer ACTIVALL

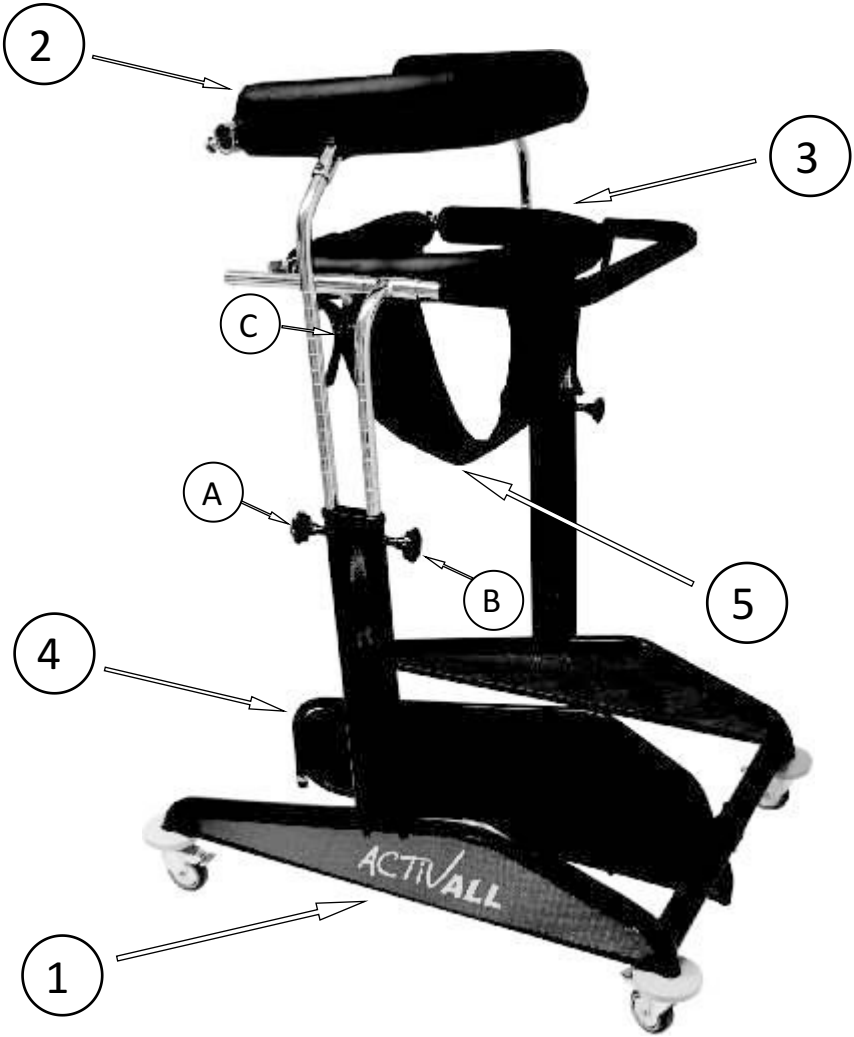
Verticalizer ACTIVALL is available in 5 sizes.

ACTIVALL		1	2	3	4	5
width of base/length of base (cm) ń with buffer and rear wheel's break	A/B	64x81	68x91	68x91	72x97	78,5x103
internal width of armpit and hip camping-ring (cm)	C	24	26	29	33	40
internal depth of armpit and hip camping-ring (cm)	D	21	23	25	28	34
distance between base and armpit clamping-ring (cm)	E	57-76	83-101	91-118	103-133	117-162
distance between base and hip clamping-ring (cm)	F	43-58	67-84	76-101	83-113	98-144
maximum weight		25 kg	40 kg	60 kg	80 kg	95 kg



5. Standard accessories of each verticalizer ACTIVALL

- frame with rotating wheels equipped with brakes (1)
- chest camping-ring with upholstery (2)
- hip camping-ring with upholstery (3)
- separator of lower limbs with upholstery (4)
- hanged harness for pelvis (5)

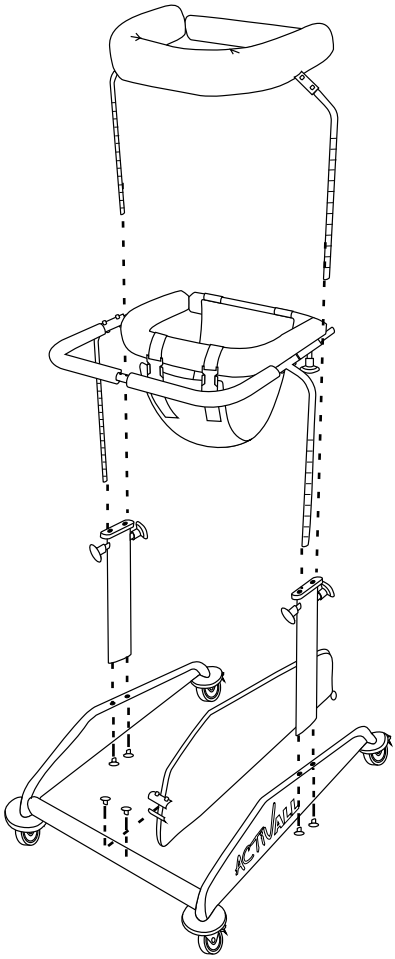


A, B, C ń regulating screws

6. Additional equipment (the instruction of assembly is attached separately)

- table
- forearms stabilizers (armrests with handle)
- front wheels with a blockade of ride direction
- wheels with rubbing breaks
- rear wheels with a blockade of backing

7. Assembly of verticalizer ACTIVALL



8. Preparation to use ń safety measures

Verticalizer ACTIVALL will correctly fulfill its function if it is adjusted to growth and weight of patient's body. Therefore during the purchase you should pay attention to the parameters (size 1,2,3,4 or 5) given on page 4. Regulation and adjustment should be always carried out by authorized service agent - therapist. The main principle of adjustment the device to the patient is maximum feeling of safety.

Safety measures:

1. Verticalizer ACTIVALL should be used according to the recommendations placed in this instruction.
2. Before use:
   - make sure that all units are in working order and correctly installed and the device does not show any signs of cracks or deformations,
   - check that the screws, nuts or other screwed connections are not slacken,
   - check the functioning of clamping-rings' locks,
   - check the brakes and wheels functioning,
   - make sure that the movable units are stable and blocked.
3. The device should not be pulled on, jerked or turned over especially if the patient stands in it.
4. The verticalizer ACTIVALL should not be used unless a trained member of a family or someone entitled to take care of disabled child is around.
5. It should never be used on unstable ground, stairs or steep slopes and also should not be left on sloping surfaces.
6. The device cannot be used if is damaged or any of its part is missing.
7. Although the device and the upholstery are made of fire-resistant materials, please pay your attention when approaching to sources of fire or sources of high temperature during exercises.
8. It is absolutely forbidden to use the device by a patient who is influenced by alcohol, intoxicants, drugs and other substances which can have a negative influence on patient's sense of balance or consciousness.

AKCES - MED Ltd. sell the device technically efficient, free of constructional, assembly or material defects etc.
Verticalizer ACTIVALL is covered by 24 months guarantee as of the day of purchasing the product by a patient.

Manufacturer is not responsible for damage in the following cases:

- **result of servicing the verticalizer by unskilled staff**
- **using verticalizer during absence of qualified staff**
- **incorrect installing the units and accessories**
- **modifying the units independently**
- **using not original units and accessories**
- **natural abrasion and wearing away of units (upholstery, wheels etc.)**
- **damage as a result of incorrect use (concerning unsuitable load and size selection of verticalizer to the given patient)**
- **not complying with the principles contained in this instruction.**

The conditions of guarantee are given in details on guarantee card which is attached to verticalizer.

WARNINGS:

- special caution should be kept during unpacking the device (cutting of package) in order not to damage the upholstery
- assembly of verticalizer should always be made by an entitled person (salesman, dealer) or medical staff accordingly trained
- dynamic verticalizer ACTIVALL is the equipment for individual use
- verticalizer ACTIVALL should be operated by persons who have read and learnt the instruction manual precisely
- verticalizer ACTIVALL should be operated by entitled persons such as: the rehabilitants, doctors of rehabilitation and qualified staff after a previous training
- verticalizer ACTIVALL may be used both on rehabilitation squads and in patient's house in the presence of suitably trained persons only.

Additional information:

- cleaning of the verticalizer should be performed in accordance with the instruction "Maintenance and cleaningî section (page 12)
- in case of any incident or damage please contact the dealer who sold the product

9. Patient's preparation

Before any action with the verticalizer every patient is obliged to comply with the following recommendations:

1. Footwear should be deep, highly-laced and should stabilize ankle. It is recommended to use orthopeadic footwear.
2. Clothes should be casual and convenient, airy, not limiting movements; sport wear (for physical exercises) is the best one.
3. Any drains, bags, catheters etc., if they are applied, have to be well protected in order not to fall out, move, shift and not to disturb while standing in straight position.
4. In case of using corset, girdle, collar, orthopeadic footwear or orthosis you should put them before exercises in the verticalizer.
The decision to define form of rehabilitation and use particular orthopeadic article must be always made by a doctor.
5. To keep hygiene and to avoid body's attritions you should not practice in the device without clothes fully covering that parts of your body which touch the upholstery.

10. Basic rules of adjustment verticalizer by a user

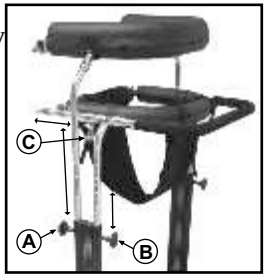
The adjustment of verticalizer to the patient should be always made by suitably trained staff .
Suitably trained persons have to assist patient while doing exercises.

Before use of verticalizer you should block the wheels' brakes and unlock hip clamping-ring and chest clamping-ring.
Not blocking the wheels of verticalizer can cause its shifting while uprising, which results in patient's fall, breakage or body's injury.
During coming into verticalizer or getting out of it you mustn't rest on rear clamping-rings' locks while they are being opened.
The attempts of overloading the opened locks of clamping-ring can cause a fall of device or deformation, which results in incorrect functioning of fastener lock.

After patient's verticalization close the rear blockades of both clamping-rings and adjusts the following elements:

Chest camping-ring ń perpendicular regulating
Height of chest camping-ring depends on patient's control over his chest. If control is good, patient keeps upright position, it does not require his big effort and patient feels safe, the clamping-ring can be fixed below. Nevertheless, in such case a walking process should begin with fixing the clamping-ring under one's arm and then you can gradually level down.
To regulate the height of chest clamping-ring use knobs A.

Hip camping-ring - perpendicular and horizontal regulating
Hip camping-ring should be fixed at the level of trochanter of lower limbs (to regulate perpendicularly use knobs B).
After fixing height you must regulate position of hip camping-ring using knobs C (regulation forward and backward). The proper position of trunk and pelvis depends on precise adjusting.
The ideal position is one line of arms, trunk and hips.



CAUTION!
While regulating the height of the hip clamping-ring and chest clamping-ring you cannot exceed the double lines on cantilever.

If the abovementioned activities are finished close pelvis' harness protecting from patient's fall, by placing it between patient's legs and fastening front buckles. (The device is safe and will remain solid and stable even if patent loses his consciousness).
While buttoning buckles please place your attention on characteristic sound "CLICK" which informs about correct fastening.
Pelvis' harness cannot be treated as a seat, it serves as a protection from the fall only in case of faintness.
Straight position is safe and comfortable. While standing in this position patient is being adapted to the vertical position as well as sense of equilibrium, internal organs, circulation system are being adopted to the new conditions and to bigger load.
Patient can stand in straight position quite long time, can simultaneously do exercises or simple everyday-life activities etc.

To facilitate simple everyday-life activities we recommend installation of a table (ADDITIONAL EQUIPMENT). It possesses the regulation of height and angle of inclination and surely it will be useful to put a book, a cup or laptop on it.
During exercises and walking the table must be disassembled!

Feet separator
In cafe of using the device by a person who has tendency to cross lower limbs, it is recommended to use separator. Assembly has been shown on picture (page 6).

11. Learning to walk

If the patient feels well you can unblock the brakes and start practicing.
By shoving the trunk and pelvis ahead, with both hands on handles (handles are additionally protected from sliding of hands and coated with washable spongy material) or on supports (ADDITIONAL EQUIPMENT). Then the equilibrium point will Shift forward, which stimulate walking process.
This position should not be forced, because then can bring about the opposite effect.

The first steps should be done forward and then backward and finally to diverse directions.

While walking, firstly normal steps should be done and then fester or slower steps.
We recommend to use special paths in order to help in orientation for both courageous and not courageous type of patients.
After practicing in verticalizer ACTIVALL patient must return safely on wheelchair, chair, armchair, bed etc.
Patient cannot leave verticalizer independently.
To leave verticalizer the following should be done
(hints for doctors of rehabilitation):
1. Block the wheels of verticalizer using brakes.
2. At the back of verticalizer put the wheelchair, chair, armchair etc.
3. Unfasten opening of both pelot-pads
4. Seat patient on wheelchair, chair, armchair etc gently.

Therapist is obliged to patient's insurance at side or at the back.

CAUTION!
You should pay your special attention to block the wheels of wheelchair and protect the chair or armchair before patient is going to seat on it. Backing off of the seat can cause patient's fall or injuries.

12. Maintenance and cleaning of verticalizer ACTIVALL

Verticalizer - as an individual orthopedic supply and a medical device, should be kept clean and used in compliance with the manufacturer's recommendations.
The device should be kept in clean, dry and ventilated room in the temperature of 15-35°C and relative humidity not exceeding 80 %.
Preservation and cleaning of the device have to be performed at least once a month.
Regular cleaning and preservation of verticalizer are indispensable to maintain its correct functionality and safety.

Maintenance of wheels
It is recommended to clean the wheels and remove hair, dust, ash etc. at least once a month. You should also grease the wheels with special spray. Manufacturer recommends to use WD-40 (a free of charge sample has been attached to the article).

Maintenance of construction and upholstered units
Whole construction and upholstery of ACTIVALL should be cleaned with soft cloth moistened in diluted alcohol, after cleaning should be dried gently. Any signs of corrosion should be reported to the dealer.
In case of using verticalizer by many patients (in the hospitals, rehabilitation centres or other places), and the rules of the abovementioned institutions are not different, both hand handles should be disinfected before transferring the device to next person (the best way is to wipe with alcohol). Absolutely impermissible is direct contact the upholstery with uncovered patient's body.

Harness for pelvis should be washed by hand using delicate washing agents. The temperature of water cannot exceed 40°C.

Dry in spread position in room temperature.

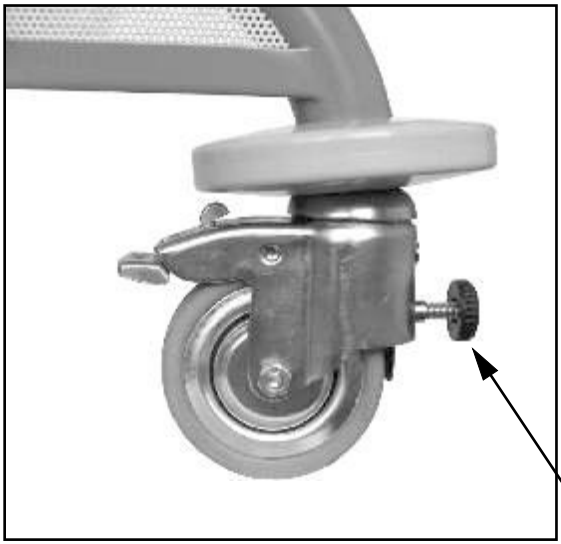
Only in case of exact compliance with all above recommendations, the responsibility for correct work of the verticalizer is on Manufacturer.

It is not allowed to clean, change units, parts and conserve the verticalizer while it is being used by the patient.
The responsibility for any other activities with ACTIVALL is on user. Manufacturer is responsible only for original and hidden defects or technical damages occurred during the correct exploitation of the article.

In case a particular unit needs to be changed or serviced or the device needs to be exchanged please contact the dealer who sold the product.

Dynamic Verticalizer ACTIVALL

Additional equipment - Wheels with a rubbing break



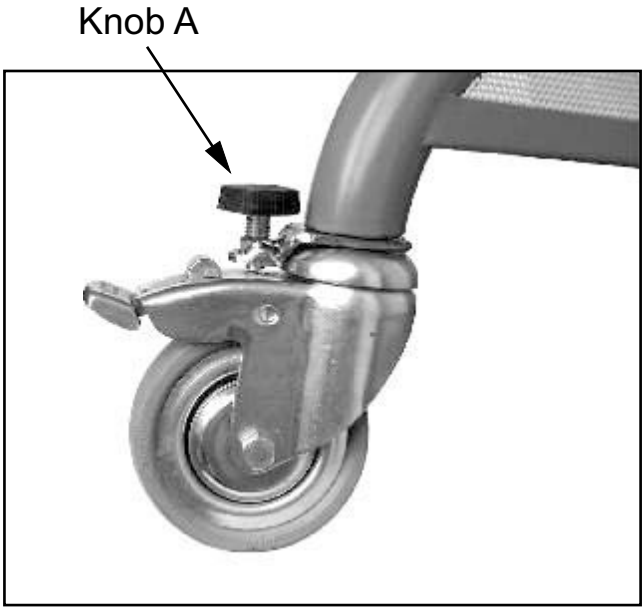
Using the wheels with a rubbing break enables patient to fit the speed of moving in verticalizer.
It is of importance during the first exercises in verticalizer.

Knob A regulates strength of stress of a metal strip which brake the rotating wheel. While first steps in verticalizer ACTIVALL it is recommended to use rubbing break in order to move slower.

When patient gets more confidence, the resistance of break can be reduced.

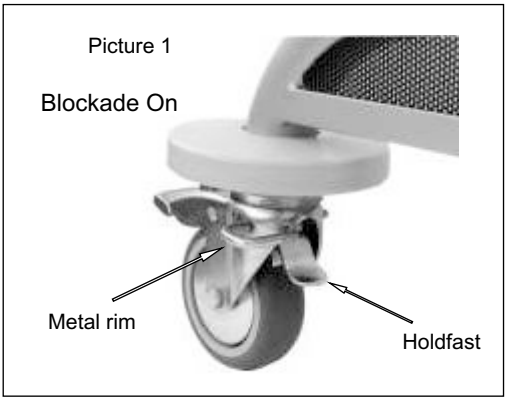
Dynamic Verticalizer ACTIVALL

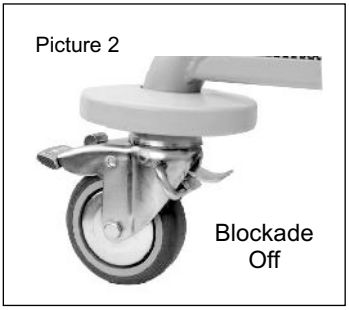
Additional equipment - wheels with a blockade of ride direction

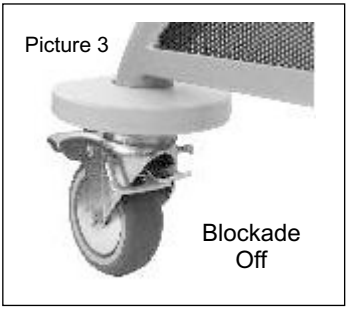


Using the wheels with a blockade of ride direction is of great importance while first steps in the verticalizer.
Screwing tight the knob A blocks a bend of wheels and patient can move forward only.

Additional option
- blocking of wheels' regressing ride







Using of regressing ride wheels is very usefull in learn walking when patients are start to walk.
To unblock blockade please lift up a holdfast and push metal rim under the holdfast (picture 2 and 3).
To block againg stick out a metal rim from under the holdfast (picture 1).

Dynamic Verticalizer
ACTIVALL
Additional equipment - table

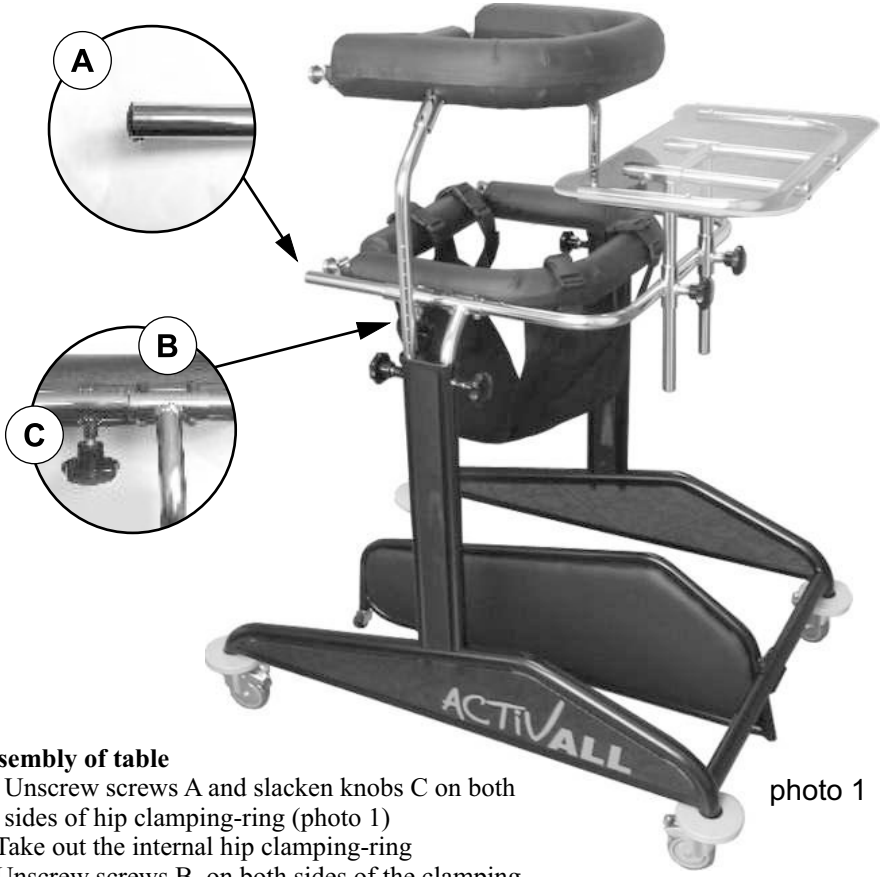


photo 1

Assembly of table

1. Unscrew screws A and slacken knobs C on both sides of hip clamping-ring (photo 1)
2. Take out the internal hip clamping-ring
3. Unscrew screws B on both sides of the clamping-ring
4. Pull out the bail of clamping-ring
5. In this place put the new bail, screw the screws B, put the internal clamping-ring and screw the screws A.

The table possesses two ways of regulation:
Knobs D - enable to regulate up-down
Knobs E - enable to regulate front-back (photo 2)

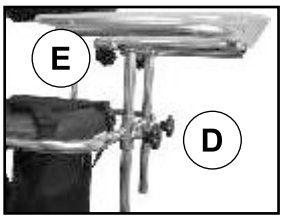


photo 2

ORTHOPAEDIC DEVICES MANUFACTURER

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Authorised Dealer

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